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**Bard Medical Division**
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

NOV 1 0 2009

BARD

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

### A. SUBMITTER INFORMATION:

| | |
|---|---|
| Submitter's Name: | C. R. Bard, Inc.<br>Bard Medical Division |
| Address: | 8195 Industrial Blvd.<br>Covington, GA 30014 |
| Contact Person: | Ms. Julie Bassett |
| Contact Person's Telephone Number: | 770-784-6375 |
| Contact Person's Fax: | 770-385-4706 |

### B. DEVICE NAME:

| | |
|---|---|
| Trade Name(s): | Alyte™ Y-Mesh Graft |
| Common/Usual Name: | Surgical Mesh |
| Classification Names: | OTQ – Mesh, Surgical, Polymeric |
| CFR Reference: | 21 CFR 878.3300 |
| Classification Panel: | General and Plastic Surgery |

### C. PREDICATE DEVICE NAME:

Trade Names: Mpathy Medical Devices Ltd. Minimesh® Polypropylene Mesh - K053361 and
American Medical Systems Y-Mesh Graft – K033636, K040521

### D. DEVICE DESCRIPTION:

The Alyte™ Y-Mesh Graft is a surgical implant used in the repair of vaginal wall prolapse. The graft is comprised of a lightweight/ultra-lightweight, non-absorbable monofilament polypropylene mesh. The graft is designed such that the surgeon will be able to alter/trim the graft to different sizes as required to fit each patient's anatomical requirements without unraveling. The graft is available in a Y shape as a convenience to the physician.

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**E. INDICATIONS FOR USE:**

The Alyte™ Y-Mesh Graft is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

**F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:**

The subject Alyte™ Y-Mesh Graft has the same intended use and technological characteristics as the predicate devices.

**G. PERFORMANCE DATA SUMMARY:**

The appropriate testing to determine substantial equivalence was completed. This includes testing in accordance with *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 22, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Inc.
% Ms. Julie Bassett
Regulatory Affairs Specialist II
8195 Industrial Boulevard
COVINGTON GA 30014

SEP 28 2012

Re: K090739
Trade/Device Name: Alyte™ Y-Mesh Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: September 18, 2009
Received: September 23, 2009

Dear Ms. Bassett:

This letter corrects our substantially equivalent letter of November 10, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090739

**1.1** *Indications for Use Statement*

510(k) Number (if known): K090739

Device Name: **Alyte™ Y-Mesh Graft**

Indications for Use:

The Alyte™ Y-Mesh Graft is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090739

(Recommended Format 11/13/2003)